Background of the Invention

Stoppers for use in medical packaging have to exhibit at least two characteristics:

- holding the medicine tightly in the packaging

- not leaking substances from the stopper material into the medicine.

Unfortunately the materials used for stoppers normally exhibit one but not both of the above characteristics. The stopper of the present invention exhibits both.

USC 102(b) rejections

In the previous office action, the Examiner rejected all claims under 35 USC 102(b) in view of Kasai et al. The claims have been amended to incorporate the limitations from previous claim 29.

The present invention relates to a stopper material of two components, wherein a balance of the two above-mentioned characteristics has been provided.
The stopper as defined in the present claims is an injection-mouldable material made of a combination of a butyl-based rubber (70-90 % by weight) and a thermoplastic polymer (30-10 % by weight), wherein the thermoplastic polymer is selected from polyethylene and polypropylene.

Butyl-based rubber is a soft material (Shore A hardness of 45-50, see page 9~ lines 12-13) leading to good tightening characteristics, however it has been found that butyl-based rubber is also known to leak substances into the medicament in the packaging. By blending a thermoplastic polymer into the butyl-based rubber the hardness increases and the leakage into the

medicament decreases, however the tightening is still acceptable for packaging purposes of fluid medicaments.

The stopper of Kasai comprises up to four different components:

- Butyl-based rubber (30-90 % by weight, preferably 50-70 %, by weight, and in all of the examples the butyl-based rubber is included with 60 % by weight)
- Thermoplastic elastomer (10-70 % by weight)
- Optionally an olefin-based polymer (0-30 % by weight, preferably 10-20 % by weight)
- Optionally a filler (0-80 % by weight)

The two first mentioned components are compulsory, while the two latter are optional.

The stopper of Kasai is described to be suitable for use with a vacuum blood collecting tube, which is why it is emphasized that the stopper has a satisfactory gas barrier property. There is no description that the stopper may be used in a medical packaging. Medical packaging of fluid medicaments, such as insulin, requires that leakage from the stopper is reduced for a prolonged storage time.

In Kasai the thermoplastic elastomer include: Polyester elastomers, polyolefin elastomers, such as ethylene-propylene copolymers or ethylene-propylene-non-conjugated d ien e copo lymers, partially cross-linked ethylene-propylene rubbers, propylene graft ethylene-propylene rubbers and isobutylene graft polyethylenes, styrene-based elastomers, polyamide-type elastomers, and 1 ,2-polybutadiene.

The thermoplastic elastomer does not comprise a polyethylene or a polypropylene, such as the thermoplastic polyolefin of the present invention.

In addition to the butyl-based rubber and the thermoplastic elastomer, the stopper of Kasai may further include an olefin-based polymer, including propylenes, and ethylene5. The olefin-based polymer is added in an amount of up to 30 %, by weight, preferably 10-20 % by weight.

The Examiner states, that Kasai et al teaches that the bromobutyl rubber is blended with up to 30 % polypropylene or polyethylene. However, in this statement the Examiner leaves out, that the blend in addition hereto comprises the thermoplastic elastomer.

Accordingly, Kasai et al. does not teach a stopper of a blend of butyl-based rubber and propylene or of butyl-based rubber and ethylene without the thermoplastic elastomer. Therefore, the present invention as defined in the amended claims is neither anticipated nor obvious in view of Kasai et al.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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